REMARKS

Claims 10-13 and 16 have been amended with this Response as shown above. Support for the amendments can be found in the specification and claims as filed, for example, on page 7, lines 27-28; page 15, lines 23-31; page 16, lines 1-10; page 26, lines 28-31; and page 27, lines 1-21. No new matter was added.

Applicants respectfully request entry of this Amendment under 37 C.F.R. § 1.116, which places the claims in condition for allowance or in better form for appeal. The proposed amendments do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner since all of the elements claims were either earlier claimed or inherent in the claims as examined. Applicants respectfully submit that this Amendment should allow immediate action by the Examiner.

Applicants thank the Examiner for the telephonic interview conducted on November 6, 2003. The substance of the interview is set forth in detail below.

All pending claims were discussed. The Examiner contends that mouse and human BAFF sequences provided in the specification are not sufficient to enable antibodies specific to other species. Applicants respectfully disagree. Although Applicants do not concede that the claim language violates 35 U.S.C. § 112, ¶1, in order to expedite prosecution, Applicants have agreed to amend the claims to recite "anti-BAFF antibody that recognizes human (SEQ ID NO:1) or murine (SEQ ID NO:2) BAFF." Applicants note that antibodies directed against a protein from one species may, and often do, cross-react with orthologs of that protein from other species, particularly if there is a high percent identity with a respective ortholog. Additionally,

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antibodies against a protein typically also recognize variants of that protein, including, for example, fragments and modified sequences, so long as the antigenic determinant(s) remain(s) intact. The claims, as amended, encompass all such antibodies.

During the interview, the Examiner acknowledged that abstracts by Furie et al. and Wendy et al. (American College of Rheumatology (ACR), 67th Annual Scientific Meeting, Orlando, FL, October 23-28, 2003, Abstracts #922 and #1537, respectively) provide sufficient evidence to show that B-cell growth is inhibited by anti-BAFF ligand antibody. To complete the record, Applicants submit copies of the Furie and Wendy abstracts with this response.

The Examiner requested that Applicants provide additional evidence regarding inhibition of immunoglobulin production. Accordingly, with this response, Applicants submit the Declaration of Dr. Susan Kalled. The Declaration provides further evidence that BAFF antagonism leads to inhibition of immunoglobulin production and/or B cell growth/maturation in an animal, as claimed. Dr. Kalled and her colleagues evaluated treatment of BAFF transgenic mice with a soluble form of a BAFF receptor, BCMA (B cell maturation antigen). Dr. Kalled provides experimental evidence that total serum immunoglobulins (Ig), splenolomegaly, and the numbers of MZ and mature B cells are significantly inhibited by the treatment with the BAFF receptor. *See* ¶10. These therapeutic effects are attributed to sequestration of BAFF. *Id.* Dr. Kalled further states that administration of soluble forms of other BAFF receptors or anti-BAFF antibody that recognizes human and/or mouse BAFF is expected to reduce immunoglobulin production and B cell growth. *See* ¶11.

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Additionally, Applicants submit an article by Kayagaki et al. (Immunity, 10:515-524) which demonstrates that treatment with anti-BAFF antibody is expected to reduce total Ig and autoantibody production in yet another animal model. Kayagaki evaluated treatment of NZB/WF1 mice with a soluble form of a BAFF receptor, BAFF-R-Fc (also known as BR3). Kayagaki shows that mice treated with BAFF-R-Fc exhibit a reduced proteinuria (which is indicative of immunoglobulin production) and a corresponding reduction in the anti-dsDNA autoantibody titer (Figs. 4C and 4B). Although Kayagaki did not use an anti-BAFF antibody in the study, those of skill in art would expect results with an anti-BAFF antibody to be similar due to the structural and functional similarity between BAFF-R-Fc and an anti-BAFF antibody.

In view of the foregoing amendments and remarks, Applicants believe that the claims are in condition for allowance. Should the Examiner require further clarification, the Examiner is welcome to call the undersigned at (617) 452-1650.

Please grant any extensions of time required to enter this response and charge any additional required fees to deposit account 06-0916.

Respectfully submitted,

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Dated: January 16, 2004

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